Stabilizer Device for Intra-Cardiac Echocardiography (ICE) to Assist Structural Heart Interventional Procedures

Product Design Specifications

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Lab 303

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Function

This device will be used for the stabilization of intracardiac echocardiography (ICE) equipment during structural heart intervention procedures. In order to clearly visualize a patient's cardiac structure, the ICE catheter and handle must remain still. According to the client, Dr. Amish Raval, even 3-4 mm of movement at the handle of the catheter can significantly affect the visualization of the ICE. Therefore, this device must function as an adjustable support fixture for the handle of the ICE catheter. This device will replace the current stabilization method used by the client, which typically consists of either a technician holding the handle of the catheter in place or wet towels laid on top of the catheter handle. Implementation of this stabilization device will enable the ICE catheter to remain in place while also allowing the physician to make adjustments to the catheter position throughout the procedure.

Client Requirements

The stabilizer device must:

- Have an adjustable height of 75 to 200 mm
- Have an adjustable angle of 0° to -30° from parallel to the operating table
- Allow the ICE handle to translate approximately 75 mm towards and away from the point of insertion
- Allow for the manipulation of the ICE handle controls while it is secured/resting in the stabilizer
- Be able to be used for both the left and right legs
- Not interfere with the therapeutic device
- Be compatible with different brands/models of ICE handles

- Be made of metal and re-sterilizable via ethylene oxide, or be made of plastic, manufactured sterilized and disposable
- Cost less than $300 to manufacture

The research and development budget for the team is $1,000.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:* The device must be able to securely hold the ICE handle in place while allowing for the manipulation of the ICE controls. It must also allow for vertical adjustment of the handle from 75 to 200 mm and angular adjustment of 0° to -30° from parallel to the operating table. It should as well allow for about 75 mm of translational movement of the handle toward and away from the point of insertion only when desired by the operator. In addition, it should be able to withstand common forces it may encounter in a surgical setting, such as bumps of the table.
    b. *Safety:* The stabilizer must be able to hold the catheter autonomously without the catheter being moved or displaced. Such displacements would provide procedural complications such as perforation of an artery or aorta or an atrioesophageal fistula formation (caused by thermal damage from the catheter in the esophagus) [1]. If the aorta is perforated, it causes immediate death in 40% of patients [2]. Additionally, the stabilizer must be properly stabilized between uses. Without proper sterilization, the device could cause serious infection or disease to the patient as the patient's femoral artery is exposed.

c. *Accuracy and Reliability:* The device must allow complete access to the ICE catheter device's controls. The device must not allow for more than 2 mm of movement of the ICE catheter as even 3 mm of movement can misalign the system. The device should be able to work with any ICE catheter on the market and either be re-sterilizable or sterile and disposable.

d. *Life in Service:* The life in service of the stabilizer instrument is synonymous with the use duration of the device. The instrument must withstand a use duration of 30 minutes up to 3 hours in accordance with the typical length of cardiac catheterization procedures [3].

e. *Shelf Life:* The device must either be single-use or reused for numerous procedures. If a reusable instrument is designed, the device must be reusable for at least 500 procedures or 5 years, depending on the waste/device recycling procedures of the hospital or clinic in which it is used. Stainless steel surgical instruments can typically be used for over 20 years and thus the device may have the potential to be used beyond the required lifetime [4].

f. *Operating Environment:* This device will be utilized in catheterization laboratories (cath labs) which are sterile environments. All parts of the stabilizer above the sterile drape must be sterile, meaning the device must be manufactured and shipped as sterile and be disposable or must be re-sterilizable via ethylene oxide gas [5].

g. *Ergonomics:* The device must be fully functional with no additional human stabilization to the device. It should not interfere with any surgical procedures and must allow access to the ICE handle controls for the user to operate.

h. *Size:* The device should be as small as possible while maintaining its essential functions so as to not interfere with the other surgical procedures the ICE is supporting. If the route of a table mounted device is chosen, the device should not take up more than a 100 mm x 200 mm x 380 mm. If another design route is chosen, such as an articulating arm, the dimensions may vary as necessitated by the design. It must be able to secure a handle with a diameter of 46.45 mm at the widest and 25.14 mm at the narrowest, with some additional flexibility for adjustment of the device when used with different ICE models. There is limited space in the catheter lab for equipment; therefore, the device should take up a minimal footprint to allow the operator more room to perform the procedure and to leave space for other equipment.

i. *Weight:* As the device is intended to stabilize the ICE by securing its handle, it must have a weight of at least 1 kg to resist bumps and forces that would otherwise knock the ICE out of place. The device must not be overly heavy, however, as it should not be burdensome to set up or move; thus, the device should not weigh more than 6 kg. If alternative methods are used to secure the stabilizer to the table such as a clamp or suction cup, it could be acceptable for the device to weigh less than 1 kg.

j. *Materials:* The device must be made of a material that can withstand ethylene oxide gas sterilization. Specifically, the material must withstand a sterilization cycle of 1-6 hours at 37-63 °C and relative humidity of 40-80% [6]. Such materials could include stainless steel or thermoplastics such as PEEK; however, most commonly-used materials are highly compatible with ethylene oxide.

Additionally, the material must be compatible with the chosen method of fabrication, which could potentially include CNC machining or 3D printing.

k. *Aesthetics, Appearance, and Finish:* The geometry and surface finish of the device must be compatible with gas sterilization if a reusable design is chosen; alternatively, the device should be sterile and disposable. The device should not provide a visually distracting appearance to the surgical procedures.

2. Production Characteristics

a. *Quantity:* One functional prototype of the device will be developed in order to gauge if the device integrates with the protocols for the procedure and test if the device meets all requirements.

b. *Target Product Cost:* According to the client, the device must cost under $300.

3. Miscellaneous

a. *Standards and Specifications:* As defined by the FDA in the Code of Federal Regulations, Title 21, Part 880.5210, an intravascular catheter securement device is a Class I (general controls) medical device [7]. While the FDA does not specifically call out an intracardiac catheter stabilization or securement device, a similar stabilization accessory for the MitraClip System is a Class I device [8]. Class I devices must only meet the requirements of the General Controls provisions of the CFR Title 21, Subchapter H in order to prove the device's safety and efficacy [9]. Additionally, ISO 13485, which includes requirements for regulatory purposes of medical devices, states that the design and development process outputs must be documented in a form suitable for verification against the design and development requirements [10].

b. *Customer:* The customer of this device requires that the device improves upon the current method of ICE catheter stabilization. Customers for this product include physicians and hospital or medical clinic staff. The device must streamline the process of performing interventional heart procedures with the goal of improving accuracy and efficiency of the procedures.

c. *Patient-Related Concerns:* The device must be inclusive for use with all patients. Patients undergoing structural heart intervention procedures may be likely to have increased waist circumference or waist to hip ratio as these metrics are predictive of cardiovascular disease [11]; thus, the functionality of the device must be independent of patient size. Additionally, the device must not cause discomfort for the patient during the procedure.

d. *Competition:* There are many ICE catheter stand and clamp systems on the market. The Abbott MitraClip and Triclip are held up by a stand that allows for the attachment of a mitral valve replacement device at an angle to allow for the user to easily access the controls [12]. Furthermore, the Edwards EVOQUE comes on a base plate that has a stabilizer to hold a tricuspid valve replacement device. This also comes with adjustable leg height and clamps [13]. Both the EVOQUE and the MitraClip are similarly sized to ICE catheters.

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